

REMARKS

Claims 1-5 remain in this application. Claims 1 has been amended to reflect the elected subject matter and more precisely claim Applicants' invention. Entry of the amendments and allowance of the claims in view of the amendments are respectfully requested.

Rejection of Claims 1-3 and 5 under 35 USC §102(e) over Bonjouklian et al. US 7,320,995

Claims 1-3 and 5 stand rejected under 35 USC §102(e) as allegedly being anticipated by Bonjouklian et al. (US 7,320,995). The Examiner points out specific compounds "col. 73, example 181-col. 78 example 209+ benzimidazolylimidazoles with instant R being H, or SO₂R₇, R₁ is amino and structural delineation from CA140." Applicants, respectfully assert that these compounds are not in the scope of the instant application. In the instant invention, R cannot be H and thus these compounds are not in the scope of the instant invention. Furthermore, the compounds in Bonjouklian et al. pointed out by the Examiner have W is (i). In the instant invention R is SO₂R₇ only when W is (vii), see proviso in original claim 1. Since the compounds where W is (vii) are non-elected subject matter, Applicants have cancelled this term as well as the term R is SO₂R₇. Applicants therefore contend that the compounds pointed out by the Examiner are not in the scope of the present invention and thus do not anticipate the present claims. For all of the above reasons, Applicants assert that the rejection is improper and should be withdrawn.

Rejection of Claims 1-5 under 35 USC §103(a) over Bonjouklian et al. US 7,320,995

Claims 1-5 stand rejected under 35 USC §103(a) as allegedly being obvious in view of Bonjouklian et al. (US 7,320,995). Enacted on November 29, 1999, the American Inventors Protection Act (AIPA) added subject matter which was prior art under former 35 U.S.C. §103 via 35 U.S.C. §102(e) as disqualified prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." See MPEP706.02(l)(1)I. The Bonjouklian reference qualifies as prior art under 35 U.S.C. §102(e) for the present application. Both Bonjouklian et al. and the present application were, at the time the invention was made, subject to an obligation of assignment to Eli Lilly and Company. Thus, Bonjouklian et al. is

disqualified prior art against the claimed invention, making the rejection under 35 U.S.C. §103(a) improper. Applicants request withdrawal of this rejection.

Applicants assert that even if Bonjouklian et al. (US 7,320,995) was available as a reference under 35 USC §102(e) that the Examiner has failed to make a *prima facie* case of obviousness against claims 1-5. The courts have clearly stated the requirements to establish a case of *prima facie* obviousness in new chemical compound cases. The courts have held that “structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness.” *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1990) (*en banc*). The courts have further held that in addition to structural similarity, a *prima facie* case of obviousness also requires a showing of “adequate support in the prior art” for the change in structure. *In re Grabiak*, 226 USPQ 870 (Fed. Cir. 1985). The Supreme Court, recently, affirmed that it is necessary to provide “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does” in an obviousness determination. *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). The Federal Circuit has applied this to new compound cases by stating, “in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.” *Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd.*, 83 USPQ2d 1169 (Fed. Cir. 2007).

Applicants contend that the Examiner has failed to give a reason why one skilled in the art would choose a compound from Bonjouklian et al. (US 7,320,995) where R⁴ is H as a compound to modify, particularly in view of the preferences listed in the application which do not include R⁴ is H as a preference. See column 9 at about lines 36-43. Additionally, the Examiner has failed to give any reason why one skilled in the art would be motivated to modify a known compound in Bonjouklian et al. (US 7,320,995) to a compound of the present invention. For the above reasons, Applicants assert that even if Bonjouklian et al. (US 7,320,995) was available as a reference under 35 USC §102(e), the Examiner has not met her burden of proving a *prima facie* case of obviousness and, respectfully, ask for reconsideration of the claims.

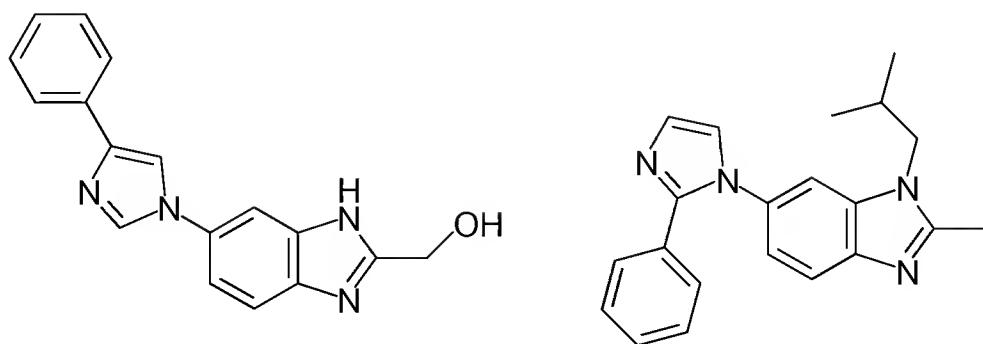
Rejection of Claims 1-5 under 35 USC §103(a) over DeNanteuil et al. US 6,040,327

Claims 1-5 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over DeNanteuil et al. US 6,040,327. The Examiner alleges that DeNanteuil “disclosed therapeutically active compounds of formula I [that are] generically embraced [by] the instant claims when X is NR, R2 is substituted imidazol, [and] R1 is linear or branched alkyl or hydroxyl (see col. 1-2). An example drawn to R1 is hydroxyl was exemplified see col. 6, example.” The Examiner further alleges that “the difference between the exemplified species and the instant claims is that the R1 is alkyl was not exemplified. The DeNanteuil '327 reference has however, exemplified variations of R1 corresponding to the broad scope of the description, [and] therefore, has fully enabled the generic scope of the reference.” Finally, the Examiner states that “One having ordinary skill in the art in possession of the DeNanteuil et al. '327 reference would be in possession of the R1 is methyl compounds. The difference between the prior art and the instant claims would be a one methyl addition. The difference of one methyl homologous chain would be considered structurally *prima facie* because decisions on such structural homologue is truly monumental. see *In re Hoch* 166 USPQ 406; *In re Shetty* 195 USPQ 753; *In re Jones* 21 USPQ2d 1941; *In re Dillon* [sic] 16 USPQ2d 1897; *In re Grabiak* 226 USPQ 870 etc.”

Applicants respectfully assert that the Examiner has failed to make a *prima facie* case of obviousness against claims 1-5. The courts have clearly stated the requirements to establish a case of *prima facie* obviousness in new chemical compound cases. The courts have held that “structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness.” *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1990) (*en banc*). The courts have further held that in addition to structural similarity, a *prima facie* case of obviousness also requires a showing of “adequate support in the prior art” for the change in structure. *In re Grabiak*, 226 USPQ 870 (Fed. Cir. 1985). The Supreme Court, recently, affirmed that it is necessary to provide “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does” in an obviousness determination. *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). The Federal Circuit has applied this to new compound cases by stating, “in cases involving new chemical compounds, it remains necessary to identify some reason that would

have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.” Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd., 83 USPQ2d 1169 (Fed. Cir. 2007).

Before applying these rules to the present facts, Applicants would like to clarify the facts. Applicants, respectfully, disagree with the Examiners characterization of the scope and content of the DeNanteuil reference. Applicants disagree that DeNanteuil “disclosed therapeutically active compounds of formula I [that are] generically embraced [by] the instant claims when X is NR, R2 is substituted imidazol, [and] R1 is linear or branched alkyl or hydroxyl (see col. 1-2).” Applicants assert that DeNanteuil does not generically disclose therapeutically active compounds of formula I where R1 is linear or branched alkyl. Applicants, further, disagree with the Examiners characterization of the difference between the exemplified species in DeNanteuil and the instant claims. Since DeNanteuil does not disclose R1 is linear or branched alkyl, Applicants reject the notion that that a skilled artisan would be in possession of the R1 methyl compound and, therefore, the notion that the difference between the prior art and the instant claims would be a one methyl addition. Furthermore, the only exemplified, phenyl substituted imidazole compounds in DeNanteuil are examples 11 and 12. Therefore, the difference between the exemplified species in DeNanteuil and the instant claims are at least 1) the removal of a hydroxyl group at the benzimidazole 2-position, 2) the addition of an alkyl at the benzimidazole N-1 position, 3) addition of phenyl at the imidazole 2-position and 4) removal of a phenyl from the imidazole 4 position (see illustration below).



US6040327
Example 12

10/597,359

Applicants argue that the Examiner has not met the requirements for a *prima facie* case of obviousness. First, the Examiner has not provided any reason why a person of ordinary skill in the art would first choose either example 11 or 12 as a compound for modification. *Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd.*, 83 USPQ2d 1169 (Fed. Cir. 2007). In fact the preferences in this reference would teach away from this choice. See column 2 lines 53-63. Second, the Examiner has not provided a reason why a person of ordinary skill in the art would make the, at least, four significant changes to transform the compound to those of the instant claim. Applicants disagree that the Examiner has met her burden of proving a *prima facie* case of obviousness and, respectfully, ask for reconsideration of the claims.

Rejection of Claims 1-5 under nonstatutory obviousness-type double patenting over Bonjouklian et al. US 7,320,995

Claims 1-5 stand rejected under nonstatutory obviousness-type double patenting over *Bonjouklian et al. US 7,320,995*. The Examiner claims that “Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are drawn to the instant elected scope when R is H or SO₂R₇ while the instant claims have R being methyl or SO₂R₇. The homologous nature of structural *prima facie* between H and methyl has been clearly delineated *supra* in sections 3 and 4 *supra*. The decisions on such structural homologue is truly monumental. see *In re Hoch* 166 USPQ 406; *In re Shetty* 195 USPQ 753; *In re Jones* 21 USPQ2d 1941; *In re Dillon* 16 USPQ2d 1897; *In re Grabiak* 226 USPQ 870 etc.”

In light of the cancellation of the term SOR₇ (discussed *supra*) in the claims, this part of the Examiner’s argument has been rendered moot. Applicants respectfully assert that the Examiner has failed to make a *prima facie* case of obviousness against claims 1-5. The courts have clearly stated the requirements to establish a case of *prima facie* obviousness in new chemical compound cases. The courts have held that “structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness.” *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1990) (en banc). The courts have further held that in addition to structural similarity, a *prima facie* case of obviousness also requires a

showing of “adequate support in the prior art” for the change in structure. *In re Grabiak*, 226 USPQ 870 (Fed. Cir. 1985). The Supreme Court, recently, affirmed that it is necessary to provide “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does” in an obviousness determination. *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). The Federal Circuit has applied this to new compound cases by stating, “in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.” *Takeda Chemical Industries Ltd. v. Alphapharm Pty. Ltd.*, 83 USPQ2d 1169 (Fed. Cir. 2007).

Applicants respectfully assert that the Examiner has failed to make a *prima facie* case of obviousness against claims 1-5. Applicants contend that the Examiner has failed to give a reason why one skilled in the art would choose a compound from Bonjouklian et al. (US 7,320,995) where R⁴ is H as a compound to modify. Particularly in view of the preferences listed in the application which do not include R⁴ is H as a preference. See column 9 at about lines 36-43. Additionally, the Examiner has failed to give any reason why one skilled in the art would be motivated to modify a compound in Bonjouklian et al. (US 7,320,995) where R⁴ is H to a compound where R⁴ is methyl. For the above reasons, Applicants assert that the Examiner has not met her burden of proving a *prima facie* case of obviousness and thus has no basis for an nonstatutory obviousness-type double patenting. Applicants, respectfully, ask for reconsideration of claims 1-5.

SUMMARY

For all of the foregoing reasons, Applicants respectfully request passage to issuance of claims 1-5.

Please charge any fees or credit any overpayment in connection with this application which may be required by this or any related paper to Deposit Account No. 05-0840.

If the Examiner has any questions, or would like to discuss any matters in connection with this application, she is invited to contact the undersigned at (317) 277-3537.

Respectfully submitted,

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